4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1857]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0751. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practice and Hazard Analysis, and Risk-Based Preventive Controls for Human Food--21 CFR part 117; Current Good Manufacturing Practice and Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals--21 CFR part 507

OMB Control Number 0910-0751--Revision

This information collection supports FDA regulations setting forth criteria and definitions applicable to human food and to animal food, as established under the FDA Food Safety and Modernization Act (FSMA) (Pub. L. 111-353). Congress enacted FSMA in response to dramatic changes in the global food system and in our understanding of foodborne illness and its consequences, including the realization that preventable foodborne illness is both a significant public health problem and a threat to the economic well-being of the food system. The purpose of the regulations is to prevent the introduction of adulterated and/or misbranded products into the marketplace and ensure the safety of both human foods and animal food in accordance with sections 402 and 403 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342 and 343). Generally, domestic and foreign food facilities that are required to register in accordance with section 415 of the FD&C Act (21 U.S.C. 350d) must comply with these requirements, unless an exemption applies. It is important to note, however, that applicability of the current good manufacturing practice requirements for animal food is dependent upon whether a facility is required to register, while the applicability of the current good manufacturing practice requirements for human food is not dependent upon whether a facility is required to register. Regulations governing human food are set forth in part 117 (21 CFR part 117), while regulations governing animal food are found in part 507 (21 CFR part 507). Respondents to the information collection are those who manufacture, prepare, pack, or hold food intended for humans or animals.

The regulations include recordkeeping necessary to demonstrate compliance with the requirements; however, respondents that meet the definition of a "qualified facility," under 21 CFR 117.3 and 507.3, are subject to reporting. To be subject to the modified requirements set forth in part 117, subpart D and part 507, subpart A for human food and animal food, respectively, respondents must attest to their status. To assist respondents in this regard, we have developed Forms FDA 3942a (Quality Facility Attestation: Human Food) and 3942b (Quality Facility Attestation: Animal Food), available for downloading from our website at: https://www.fda.gov/food/registration-food-facilities-and-other-submissions/qualified-facility-attestation.

Section 418(l)(2)(B)(ii) of the FD&C Act (21 U.S.C. 350g(l)(2)(B)(ii)) directs us to issue guidance on documentation required to determine status as a qualified facility. Accordingly, we issued a guidance for industry entitled "Determination of Status as a Qualified Facility Under part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals," also available for downloading from our website at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-determination-status-qualified-facility. The guidance discusses the content, format, frequency, and timing of submissions. For efficiency of Agency operations, we are now accounting for burden we attribute to reporting associated with Forms FDA 3942a and 3942b, currently approved under OMB control number 0910-0854, with this information collection.

In the *Federal Register* of March 16, 2021 (86 FR 14436), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Reporting	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
117.201(c); qualified facility as reported on Form FDA 3942a	37,134	0.5[2]	18,567	0.5 (30 minutes)	9,284
507.7(c); qualified facility as reported on Form FDA 3942b	1,120	0.5	560	0.5 (30 minutes)	280
Total					9,564

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Reporting occurs biennially.

Table 2.--Estimated Annual Recordkeeping Burden: Human Foods[1]

21 CFR Section; Activity	No. of Recordkeepers	No. of Records Per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
117.126(c) and 117.170(d); food safety plan and reanalysis	46,685	1	46,685	110	5,135,350
117.136; assurance records	16,285	1	16,285	0.25 (15 minutes)	4,071
117.145(c); monitoring records	8,143	730	5,944,390	0.05 (3 minutes)	297,220
117.150(d); corrective actions and corrections records	16,285	2	32,570	1	32,570
117.155(b); verification records	8,143	244	1,986,892	0.05 (3 minutes)	99,345
117.160; validation records	3,677	6	22,062	0.25 (15 minutes)	5,515
117.475(c)(7)-(9); supplier records	16,285	10	162,850	4	651,400
117.180(d); training records for preventive controls qualified individual	46,685	1	46,685	0.25 (15 minutes)	11,671
Total					6,237,142

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3.--Estimated Annual Recordkeeping Burden: Animal Food[1]

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours[2]
Subpart A--General Provisions					
507.4(d); documentation of animal food safety and hygiene training	7,469	0.75	5,579	0.05 (3 minutes)	279
Subpart C--Hazard Analysis and Risk-Based Preventive Controls					
507.31 through 507.55; food safety plan--including hazard analysis, preventive controls, and procedures for monitoring, corrective actions, verification, recall plan, validation, reanalysis, modifications, and implementation records	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart E--Supply Chain Program					
507.105 through 507.175; written supply-chain program--including records documenting program	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart F--Requirements Applying to Records That Must Be Established and Maintained					
507.200 through 507.215; general requirements, additional requirements applying to food	7,469	519	3,876,411	0.1 (6 minutes)	387,641

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours[2]
safety plan, requirements for record retention, use of existing records, and special requirements applicable to written assurance					
Total			11,635,372		1,163,258

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

Table 4.--Estimated Annual Third-Party Disclosure Burden: Human Foods[1]

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
117.201(e); disclosure of food manufacturing facility address	37,134	1	37,134	0.25 (15 minutes)	9,284

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 5--Estimated Annual Third-Party Disclosure Burden: Animal Food[1]

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
507.27(b); labeling for the animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species	330	10	3,300	0.25 (15 minutes)	825
507.7(e)(1); change labels on products with labels	1,120	4	4,480	1	4,480
507.7(e)(2); change address on labeling (sales documents) for qualified facilities	974	1	974	1	974
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified	373	312	116,376	0.01 (36 seconds)	1,163.76
507.28(b); holding and distribution of human food byproducts for use as animal food	40,798	2	81,596	0.25 (15 minutes)	20,399
Total					27,841.76

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made slight adjustments to reflect a decrease in third-party disclosure burden associated with animal food. In this submission we provide a cumulative estimate for related disclosure activities that we had previously accounted for separately.

Dated: August 31, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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